

## CLAIMS

What is claimed is:

1. A composition for coating an implantable device comprising
  - (1) a first block copolymer comprising a block having a glass transition
 

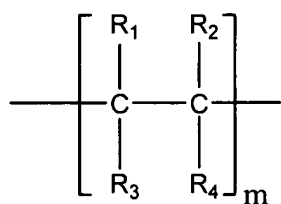
5 temperature ( $T_g$ ) below about body temperature and a second block having a  $T_g$  or a melting temperature ( $T_m$ ) above about body temperature, and
  - (2) a material selected from the group consisting of a biobeneficial polymer capable of forming a conjugate with the first block copolymer, a second block copolymer and combination thereof, wherein the second block copolymer comprising
 

10 (i) a biobeneficial component; and

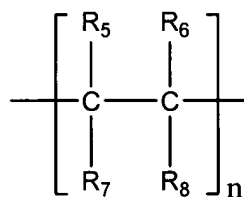
(ii) a component selected from the group consisting of components miscible with the first block copolymer and components insoluble in water,
2. The composition of claim 1 wherein the block having a  $T_g$  above about
 

body temperature has a structure of Formula I and the block having a  $T_g$  below about

15 body temperature has a structure of Formula II:



Formula I



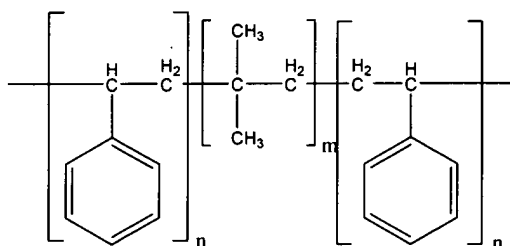
Formula II

wherein  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  are independently hydrogen, phenyl, methyl, ethyl, acrylate, or methacrylate, with the proviso that  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  can not all be hydrogen;

wherein  $R_5$  and  $R_7$  are independently methyl, ethyl, propyl, butyl, benzyl, or phenyl; and

wherein  $R_6$  and  $R_8$  are independently hydrogen, methyl, ethyl, propyl, benzyl, or phenyl.

- 5            3.        The composition of claim 1 wherein the first block copolymer has the following structure:

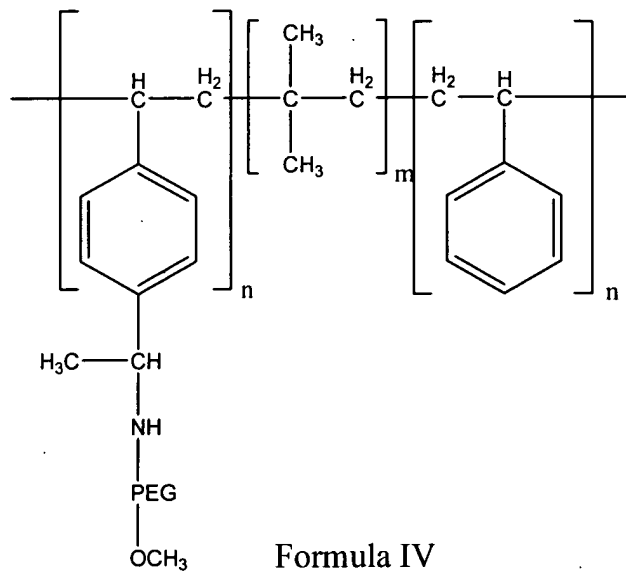


Formula III

4.        The composition of claim 1 wherein the biobeneficial polymer is covalently attached to the first block copolymer via a chemical linkage.
- 10        5.        The composition of claim 3 wherein the biobeneficial polymer is covalently attached to the phenyl ring of the structure of Formula III.
6.        The composition of claim 5 wherein the biobeneficial polymer is selected from the group consisting of poly(ethylene glycol), poly(propylene glycol), PLURONIC™ surfactants, poly(tetramethylene glycol), hydroxy functional poly(vinyl pyrrolidone), dextran, dextrin, sodium hyaluronate, hyaluronic acid, heparin, Elastin, 15 Chitosan, poly(2-hydroxyethyl methacrylate), sulphonated poly(styrene), poly(3-hydroxypropyl methacrylamide), 4-amino-2,2',6,6'-tetrapiperidine oxide, stable

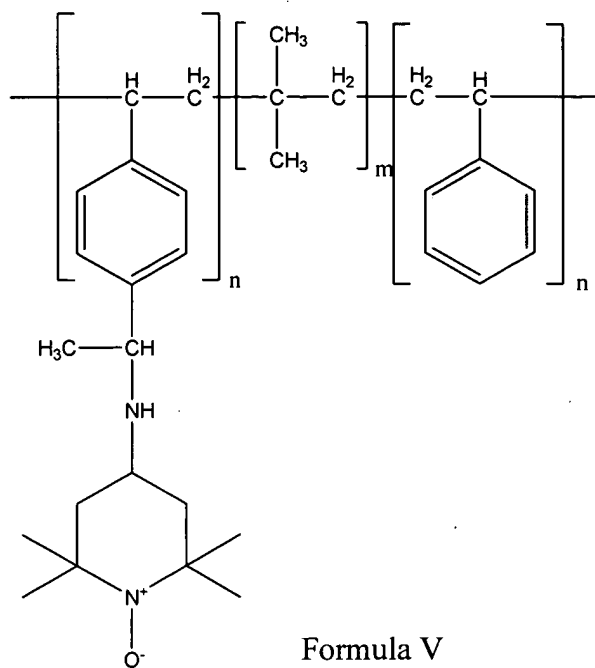
nitroxides, super oxide dimutase mimics, free radical scavengers and combinations thereof.

7. The composition of claim 6 wherein the conjugate has the structure of Formula IV:



5

8. The composition of claim 6 wherein the conjugate has the structure of Formula V:



Formula V

9. The composition of claim 1 wherein the component of the second block copolymer miscible with the first block copolymer is a hydrophobic material.

10. The composition of claim 1 wherein the second block copolymer is selected from the group consisting of polystyrene-polyisobutylene-polystyrene block copolymer (SIS), polystyrene, polyisobutylene, polycaprolactone (PCL), poly(L-lactide), poly(D,L-lactide), poly(lactides), poly(lactide-co-glycolide), poly(glycolide), polylactic acid (PLA), polyalkylene, polyfluoroalkylene, polyhydroxyalkanoate, poly(3-hydroxybutyrate), poly(4-hydroxybutyrate), poly(3-hydroxyvalerate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), poly(3-hydroxyhexanoate), poly(4-hydroxyhexanoate), mid chain polyhydroxyalkanoate, poly(trimethylene carbonate), poly(ortho ester), polyphosphazenes, poly(phosphoester), poly(tyrosine derived arylates), poly(tyrosine derived carbonates), and a combination thereof.

11. The composition of claim 1 wherein the water insoluble component is selected from the group consisting of polydimethyloxanone (PDMS), polyvinylidene fluoride (PVDF), polyhexafluoropropylene (HFP), polydimethylsiloxane, poly (vinylidene fluoride-co- hexafluoropropylene) (PVDF-HFP), poly(vinylidene fluoride-  
 5 co-chlorotrifluoroethylene) (PVDF-CTFE), poly(butyl methacrylate), poly(methyl methacrylate), poly(methacrylates), poly(vinyl acetate), poly(ethylene-co-vinyl acetate), poly(ethylene-co-vinyl alcohol), poly(ester urethanes), poly(ether-urethanes), poly(carbonate-urethanes), poly(silicone-urethanes), and poly(urea-urethanes), and a combination thereof.

10 12. The composition of claim 1 wherein the biobeneficial component of the second block copolymer is selected from the group consisting of poly(ethylene glycol), poly(propylene glycol), PLURONIC™ surfactants, poly(tetramethylene glycol), hydroxy functional poly(vinyl pyrrolidone), dextran, dextrin, sodium hyaluronate, hyaluronic acid, heparin, Elastin, Chitosan, poly(2-hydroxyethyl methacrylate),  
 15 sulphonated poly(styrene), poly(3-hydroxypropyl methacrylamide), 4-amino-2,2',6,6'-tetrapiperidine oxide, stable nitroxides, super oxide dimutase mimics, free radical scavengers and combinations thereof.

13. The composition of claim 1 wherein the second block copolymer is selected from the group consisting of SIS-PEG, polystyrene-PEG, polyisobutylene-  
 20 PEG, PCL-PEG, PLA-PEG, PDMS-PEG, PVDF-PEG, SIS-hyaluronic acid (HA), polystyrene-HA, polyisobutylene-HA, PCL-HA, PLA-HA, PMMA-HA, PVDF-HA,

SIS-heparin, polystyrene-heparin, polyisobutylene-heparin, PCL-heparin, PLA-heparin, PMMA-heparin, and PVDF-heparin.

14. The composition of any of claims 1-13 further comprising a bioactive agent.

5 15. The composition of claim 14 wherein the bioactive agent is selected from the group consisting of proteins, peptides, anti-inflammatory agents, antivirals, anticancer drugs, anticoagulant agents, free radical scavengers, Everolimus, sirolimus, sirolimus derivatives, paclitaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, nitric oxide donors, super oxide dismutases, super oxide dismutases  
10 mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), tacrolimus, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, and 40-*O*-tetrazole-rapamycin, ABT-578, clobetasol, cytostatic agents, and a combination thereof.

16. The composition of claim 15 wherein the free radical scavenger is  
15 super oxide dismutase.

17. The composition of claim 15 wherein the bioactive agent is a therapeutic drug for the treatment of restenosis.

18. An implantable device comprising a coating which comprises a composition as defined in accordance with any of claims 1-13.

20 19. The implantable device of claim 18 further comprises a bioactive agent.

20. The implantable device of claim 18 wherein the bioactive agent is selected from the group consisting of proteins, peptides, anti-inflammatory agents,

antivirals, anticancer drugs, anticoagulant agents, free radical scavengers, Everolimus, sirolimus, sirolimus derivatives, paclitaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO),  
 5    tacrolimus, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, and 40-*O*-tetrazole-rapamycin, ABT-578, clobetasol, cytostatic agents, and a combination thereof.

21.    The implantable device of claim 19 wherein the free radical scavenger is super oxide dismutase.

10        22.    The implantable device of claim 19 wherein the bioactive agent is a therapeutic drug.

23.    The implantable device of claim 18 which is a stent.

24.    The implantable device of claim 19 which is a DES.

25.    The implantable device of claim 20 which is a DES.

15        26.    The implantable device of claim 21 which is a DES.

27.    The implantable device of claim 22 which is a DES.

28.    A method of coating an implantable device comprising coating a composition as defined in claim 1.

29.    The method of claim 28 wherein the composition further comprising a  
 20    bioactive agent.

30.    A method of treating a disorder in an animal by implanting in the animal the implantable device of claim 18.

31. The method of claim 30 wherein the implantable device is a stent.

32. The method of claim 30 wherein the composition further comprises a bioactive agent.

33. The method of claim 32 wherein the bioactive agent is selected from  
5 the group consisting of proteins, peptides, anti-inflammatory agents, antivirals, anticancer drugs, anticoagulant agents, free radical scavengers, Everolimus, sirolimus, sirolimus derivatives, paclitaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), tacrolimus,  
10 dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, and 40-*O*-tetrazole-rapamycin, ABT-578, clobetasol, cytostatic agents, and a combination thereof.

34. The method of claim 33 wherein the free radical scavenger is super oxide dismutase.

15 35. The method of claim 32 wherein the bioactive agent is a therapeutic drug.

36. The method of claim 28 wherein the implantable device which is a stent.

37. The method of claim 32 which is a DES.

20 38. The method of claim 33 which is a DES.

39. The method of claim 34 which is a DES.

40. The method of claim 35 which is a DES.



41. The method of claim 28 wherein the animal is a human, and  
wherein disorder is selected from the group consisting of stenosis, occlusions  
of the arterial vasculature, and vulnerable plaque

42. The method of claim 29 wherein the animal is a human, and  
5 wherein disorder is selected from the group consisting of stenosis, occlusions  
of the arterial vasculature, and vulnerable plaque

43. The method of claim 30 wherein the animal is a human, and  
wherein disorder is selected from the group consisting of stenosis, occlusions  
of the arterial vasculature, and vulnerable plaque

10 44. The method of claim 31 wherein the animal is a human, and  
wherein disorder is selected from the group consisting of stenosis, occlusions  
of the arterial vasculature, and vulnerable plaque.

45. The method of claim 32 wherein the animal is a human, and  
wherein disorder is selected from the group consisting of stenosis, occlusions  
15 of the arterial vasculature, and vulnerable plaque.

46. The method of claim 33 wherein the animal is a human, and  
wherein disorder is selected from the group consisting of stenosis, occlusions  
of the arterial vasculature, and vulnerable plaque.

47. The method of claim 34 wherein the animal is a human, and  
20 wherein disorder is selected from the group consisting of stenosis, occlusions  
of the arterial vasculature, and vulnerable plaque.

48. The method of claim 36 wherein the animal is a human, and

wherein disorder is selected from the group consisting of stenosis, occlusions of the arterial vasculature, and vulnerable plaque.

49. The method of claim 37 wherein the animal is a human, and wherein disorder is selected from the group consisting of stenosis, occlusions  
5 of the arterial vasculature, and vulnerable plaque.

50. The method of claim 38 wherein the animal is a human, and wherein disorder is selected from the group consisting of stenosis, occlusions of the arterial vasculature, and vulnerable plaque.

51. The method of claim 39 wherein the animal is a human, and  
10 wherein disorder is selected from the group consisting of stenosis, occlusions of the arterial vasculature, and vulnerable plaque.

52. The method of claim 40 wherein the animal is a human, and wherein disorder is selected from the group consisting of stenosis, occlusions of the arterial vasculature, and vulnerable plaque.

15 53. The method of claim 41 wherein the animal is a human, and wherein disorder is selected from the group consisting of stenosis, occlusions of the arterial vasculature, and vulnerable plaque.